Guidelines

Following the College's policy on research ethics, the main issues you should consider in putting together you research plan are:-

- What will be required of the participants?
- Is this essential for the achievement of the research aims?
- What, if any, risks might this create for participants?
- How can the risks, and the intrusion into their lives, be kept to a minimum?
- Participants must understand what they are being asked to commit to. You must ensure that the information you provide is clear and comprehensive, and that participants understand they can opt out at any time without explanation;
- You must ensure that there is no undue pressure to participate;
- If the research involves vulnerable groups, and/or the proposed participants will not be capable of giving informed consent to participate, you must ensure that they are adequately protected. You should engage with someone who is qualified to speak for them, for example, a parent in the case of children, or expert intermediation for other groups;
- You should consider whether your study is likely to be affected by any legislation and, if it is, it is your responsibility to ensure that you comply;
- Information given by participants must be protected by anonymity, unless otherwise specified and agreed in writing, and the original data must be adequately safeguarded, following the guidelines of the Data Protection Act 1998.

Operational research
It is not normally necessary to obtain ethical approval for research using anonymous data obtained in the course of supplying a service which those concerned had chosen to receive, for example customer research. So, research using student performance data, or asking students to complete a questionnaire, for the purpose of improving teaching and learning, or a survey by HR to develop a new employment benefit, would be considered part of the existing relationship between the researcher and the participants.

Use of video or CCTV
Increasingly researchers are using camera-visual methods to study human behaviour. In the first place such research has to be conducted within the terms of the Data Protection Act 1998 and the College's policy on electronic data.

Anonymity, confidentiality and attribution
The concepts of anonymity and confidentiality are separate and mean different things; unfortunately many researchers confuse them. This results in the Committee not being able to approve their applications without amendment, and hence delay.

Anonymity: means that the provider of the information cannot be identified. This requires techniques such as anonymous coding, with the code key being safeguarded appropriately such as in a locked cabinet to which a few named people only have access, or electronically protected adequately by encryption or password.

Secondary use of data: safeguarding anonymity is an issue to be considered if you are proposing to use anonymised data which has been collected and is held for other

purposes. If you are using an existing data set you must satisfy yourself that those who gave the information originally had consented to its use in the way you intend.

Confidentiality: means that information provided by the participant will not be shared with anyone (except as stated and agreed – usually in writing - with the participant) but the provider of the information is identifiable by name or by other means to those with access to the data. If this is the intention it must be made absolutely clear in the information provided to participants. It must also be made clear if participants are to be quoted and their specific permission obtained to do so.

Attribution: this means that participants agree to be quoted, on the terms which should be specified clearly in the prior information, and/or as the participant agrees with the researcher. It is entirely up to the participant to accept this or not.

Recording interviews and copyright

The problem of copyright ownership potentially arises when a researcher makes an audio or video recording, or notes down an interviewee's words verbatim. For question and answer interviews there is usually no problem, and copyright in the recording belongs to the researcher.

However, if the recording is of something which is recognisable as a work - a story, or some kind of performance (e.g. a song, a dance, a poem etc), then under English law the copyright belongs to the interviewee.

The interviewee can assign this copyright to the researcher, in advance, provided this is done by signed writing. But this raises ethical issues. The researcher now owns the rights in the recording, can exploit it commercially without the agreement of the interviewee, and might even be able to prevent the interviewee from making future recordings. It is unlikely that many interviewees will realise the significance of agreeing to an assignment.

Researchers should consider whether it is more appropriate to take a licence of this copyright. This grants the researcher permission to use the copyright work for the purposes to which the interviewee has agreed. A suitable form of words might be:

"If you agree to a recording, you grant [the researcher] permission (a licence) to use any material in the recording in which you own rights for the following purposes: [explanation of uses]"

This approach resolves the ethical issue because (a) it does not take away any rights the interviewee has, and (b) it explains properly how the researcher will use the recording.

However, if there are plans to make commercial use of the recording, eg as part of a DVD or by including a transcript in a book, then the simple licensing approach above may not be adequate to satisfy a publisher. In that case, either the interviewee needs to be approached for a further, more appropriate licence, or advice needs to be taken about how to secure the necessary rights in an ethical manner.

Guidelines on data security

1. Information stored on computers/laptops or memory sticks should be protected in accordance with its sensitivity.

1.1 At a minimum, confidential information should be stored in a password-protected ***folder***, so that a person who gains access to the computer/stick does not automatically gain access to the folder. The password should be hard to guess, and not written down in proximity to the computer/stick.

1.2 For more sensitive data, encryption technology should be used to provide a greater level of protection.

2. Online storage followed by deletion from the computer/stick can be more secure and is worth considering.

2.1 The online service provider should be chosen by relevance to the nature of the information to be stored. Commercial services such as Dropbox or Box should be adequate for low sensitivity information. Highly sensitive information should be uploaded to a College server.

2.2 Access to the online storage should be password protected and:

2.2.1 The password hard to guess and not written down; and

2.2.2 The password not saved on your computer.

2.3 Where sensitive information has to be stored on a commercial service it should be encrypted before uploading.

3. Care should be taken when using internet cafes and other open-access computers. Password entry should not be viewable by other users, and the browser cache should be cleared before leaving the computer.

4. The encryption/security built into commercial applications such as Word and Acrobat is trivial, and can be defeated with easily available software tools. Take advice on which encryption technology provides appropriate protection.

5. Backup copies need the same level of protection as main copies.

Vulnerable groups

Generally speaking, groups of people who – for a variety of reasons - are not in the position of a normal adult in society need protection to ensure they are not exploited, however unintentionally.

Parental consent must be obtained for children and young people aged 17 and under.

Disabled people, especially those with a mental disability, should only be approached through or with the support of qualified intermediaries.

The following – not an exhaustive list - would be considered to be vulnerable and requiring special care in approaching them, in providing information, and to ensure that their consent is sufficiently informed:

- Persons under 18
- Children in care
- Those with a learning disability
- Those suffering from dementia
- Prisoners
- Young offenders (16-21 years old)
- Those who could be considered to have a particularly dependent relationship with the investigator (e.g. those in care homes, students, employees)
- Those whose relationship with the researcher or with the community to be researched might be subject to peer pressure or coercion e.g. students, or patients of doctors making the approach.

Those with limited understanding of English: special care should be taken to ensure they understand what is being asked and what they are committing themselves to. If there is need for two-way translation, the research should allow for this.

CRB checks are not required for researchers unless they will be in regular and unsupervised contact with children or other groups listed above. If you think you might need CRB checks please check the website

http://www.hr.qmul.ac.uk/policiesandprocedures/recruitment/criminalrecordsbureau/docs/Criminal%20Records%20Bureau%20-%20Guidance%20for%20Departments.pdf

Whilst working in a school environment, researchers are required to make themselves aware of, and adhere to, the individual school's Child Protection Policy. If applicable, they should also make themselves aware of the individual school's policy on videoing/photography. Researchers who wish to work independently with children will be required to obtain a CRB check and to also make themselves aware of the local authority's Safeguarding Officer for Child Protection so that they are sure of who immediately to contact should any concerns arise.

Payment of participants

It is acceptable to pay participants in order to recognise that they have given up their time and/or gone to some inconvenience. However, payment should not be of such an order that it incentivises people to participate against their own best interests. So, if the risk to being involved in the research is quite high and could be damaging, you should not in effect try to influence people by offering substantial payments.

It is to be expected that you may offer reimbursement of travelling or other out of pocket expenses, whether you offer payment or not.

Recruitment and information

All communications with participants and potential participants (and parents or intermediaries where appropriate) must be succinct and clear in layman's language.

Your participants will probably know nothing about your academic discipline, and its terminology could well be meaningless. So communications must be simple, in everyday language, and short, designed to meet the needs of the particular audience. Model information sheets and consent forms are attached.

Recruitment of participants should be undertaken in such a way that participation is truly voluntary and there is no coercion, either explicit or implicit (e.g. peer group). The Committee prefers the use of indirect approaches rather than face to face individual requests to potential volunteers. Ideally individuals should be able to take a positive step to participate rather than have the discomfort of declining a direct approach. Posters, leaflets, emails, or other forms of circular (e.g. in a club members' newsletter) may be used to recruit participants.

If another organisation's premises or services are to be used for recruitment publicity, the Committee will expect the permission of the owner/person in charge or the service provider to have been obtained.

Recruitment material should describe the purpose of the study, what participants will be required to do, where and when they will need to do it, and what they will get out of their participation. Any risks should be indicated.

Recruitment publicity, as well as the information sheet and consent form, must be included in your application for QMREC approval. This includes hard copy and electronic materials, and any draft emails.

Researchers who wish to recruit Queen Mary students and/or staff need to adhere to the same high standards that they would with recruitment of outside participants. All materials must be clear and professional – including circular emails.

OPT-OUT Consent

Opt-out is not normally acceptable as an alternative to formal consent. However, there may be projects where it is acceptable subject to safeguards. Safeguards would include:

- The research is tightly managed by experienced researchers, and of good quality;
- There is a responsible intermediary, such as a school or other institution, which was advised on the approach to participants and which has given its consent;
- The subject matter is not invasive nor overly sensitive;
- The information materials are clear and comprehensive;
- Obtaining opt-in consent is hindered by logistical problems but has been attempted.

Translated Materials
Where recruitment materials will need to be delivered in a language other than English, researchers should provide translated materials along with their applications. Researchers are responsible for the accuracy of their translations and should be aware that (particularly with sensitive research) independent 'backtranslation' (rendering back into English) may be required by the Committee – with costs being met by researchers.

Typographical errors
Spelling mistakes, inconsistencies and poor proof reading are frequent causes of delay as the Committee has to return the application and require them to be corrected before being able to approve an application. Such an unprofessional standard in materials going to participants impugns College standards and is simply bad manners. So check your application and materials carefully before submitting them!

Incomplete applications
The Committee reserves the right to return any application which, although submitted within the deadline for submission, is incomplete. Researchers are strongly advised to arrange signing and counter-signing of their forms within plenty of time, and to submit applications significantly prior to the deadline whenever possible.

Reporting to the Committee
QMERC reserves the right to require a report about a study it has approved, at completion or during the study, although it does not normally do so.

Detailed guidelines and application form
Detailed guidance is set out below. This follows the questions on the QMERC application form.

Detailed guidance on the application form

1 Name and email address of applicant
Apart from the hard copy submission of the application, all communication to and from the Committee will be by email.
2 Title of study
Please be consistent throughout. If you plan to use a shorter version of the title (for instance on the consent forms or information sheet) as well as a full formal title of the project, please give both.
3 Investigators
The principal investigator (PI) is normally a member of the academic staff. The PI of a student project must be the supervisor. Generally, all correspondence about the application will be sent to the PI. For audit purposes it is necessary for the PI to list their relevant experience of research on human participants. All other collaborators/investigators should be listed, with email contact details provided.

Please specify the department of investigators and also supply contact details for the Head of Department.

4 Proposed timetable

You must receive ethical approval **before** the research can start. This means that you should check the QMERC timetable before setting your start date, and allow sufficient time for the approval process to complete. The Committee does not take responsibility for any delay to the commencement of your research.

The completion date should be stated as this determines the period for which approval will be given. If subsequently you need to extend this you should refer back to the Committee. Ethical approval is given for the stated period of the research, unless the Committee requires an interim report as a condition for continuing the approval beyond a specific point.

If the project changes after approval has been given, you must report this to the Committee in case the changes require additional ethical approval.

5 Other organisations involved

i) Please state if the research is being done on behalf of an institution other than QMUL, or is being funded, in part or in full, by another institution.

ii) If you intend to conduct research in any organisation outside QMUL you must provide evidence that the organisation concerned has given permission e.g. a letter allowing you to interview their staff.

6 Other REC approval

QMERC cannot consider any research which involves clinical procedures, or NHS patients, studies involving NHS staff or NHS premises may sometimes be viewed, but researchers will need to refer to advices on the Research Ethics Committee Webpage.

If the study involves partner organisations, you should ensure that their ethical approval is obtained is appropriate. If you have another organisation's ethical approval you are still required to seek approval from QMREC.

7 Nature of project e.g. undergraduate, postgraduate

Please specify.

8 Purpose of the research

Explain the principal research questions and the anticipated benefits. You should

also state the specific objectives of the study and where appropriate the hypotheses to be tested. For each hypothesis the primary end-points to be used should be stated. You should provide the scientific justification and background of the study within the context of present knowledge.

QMREC will scrutinise the validity of the project and principal research questions, and will not be able to give its approval if it feels that the justification for engaging in the research is unclear. Unjustified intrusion into people's lives is intrinsically unethical.

9 Study design, methodology and data analysis

Please describe and justify your project's overall design and your chosen method of data collection. Summarise the nature of the participants' involvement and the reasons for it, e.g. an interview of x length, or a questionnaire, so that it is clear to the Committee exactly what will happen to the research participant, where the interaction will take place, and the length, frequency and number of sessions.

Describe the statistical methods and/or any other relevant techniques (e.g. for qualitative research) to be used in the analysis of the results and state, if appropriate, from whom data analysis advice has been sought.

If the study is collaborative or involves another organisation the responsibilities of each party should be explained, with particular reference to the responsibilities and roles of QMUL researchers.

10 Participants to be studied

Please specify:

- Age range
- Gender mix
- Number of participants.

Investigators should justify the numbers of participants they plan to recruit and the age range and gender mix.

Please also specify if participants will be from any of the vulnerable groups and if so

how you will ensure that they are competent to consent to take part in this study:

11 Selection criteria

Specify inclusion and exclusion criteria. If you are excluding participants on the basis of age, sex, ethnicity, or any other factor, please explain why.

If the study design has been informed by statistical power calculations, please describe the basis on which this was done.

12 Recruitment (including incentives and compensation)

How will potential participants in this study be (i) identified, (ii) approached and (iii) recruited?
If you will be advertising, a copy of the advert/poster/recruitment email should be included. Recruitment literature (i.e. recruitment letter or web pages) should also be submitted.

Payments may be made to participants for reimbursement of travelling, out-of pocket expenses and compensation for time. An investigator who wishes to make any other payment must state his/her reasons for wishing to do so. Financial incentives should not be offered as a matter of course but only when the researchers can justify their use. Payments must be incentives to participate rather than compensation for undergoing risk. Incentives should not persuade a participant to volunteer against his or her better interests or judgement, nor induce a participant to risk harm beyond what is normal for that person, nor to volunteer more frequently than is advisable. Incentives should not normally be used in projects where potential participants are asked to inform researchers of medical conditions which would exclude them from participation.

13 Ethical considerations and risks to participants

Please outline any ethical issues that might arise from the proposed study and how they are to be addressed. You might want to refer to issues such as recruitment in the workplace or in other contexts where there is already a relationship between researcher and potential participant (i.e. academic and student), informed consent, the degree of confidentiality and anonymity that can be assured and circumstances in which confidentiality might be breached (see section 16 below), anonymisation procedures, protection from harm, right to withdraw, the storage of sensitive data etc.

Please note that all research projects have some ethical considerations, even if this only relates to how confidentiality will be maintained.
DO NOT LEAVE THIS SECTION BLANK.

Describe the potential hazards, risks and adverse effects, specifying the probability and seriousness in each case. Explain methods employed to reduce these risks. Describe the location where the work will be done. Please give an account of the circumstances in which participants might discontinue the study, and when the study as a whole would be stopped.

Please describe any hoped-for benefits to participants.

14 Confidentiality, anonymity, and data storage

Confidentiality
Researchers have an ethical and legal obligation to respect the confidences of research participants. This confidentiality must be made clear to participants. If the intention of the research is to disclose identifiable information about individuals this must be made clear and their specific consent obtained.

Disclosure of information anonymously, which does not reveal the identity of a research participant, is not a breach of confidence.

If it is intended to re-contact the participant at a later date, for further research or to use current research data for other purposes, this should be indicated on the information sheet.

The information sheet or consent form should state clearly if participant details are to be passed to a sponsoring company or any other organisation.

If it is possible that information might come to light for which the researcher would have a responsibility to pass to a third party (e.g. evidence of professional misconduct) the participant should be advised of this possibility in the consent form and/or information sheet.

Researchers should ensure they are aware of their obligations under the Data Protection Act (website link).

Research Records
Principal Investigators must ensure that proper records are kept throughout the active period of research. Records of personal details (names, addresses, telephone numbers) must be kept in a secure place. These records should be kept separately from research records, which should ideally be identified by a code number rather than by name. In tables of data, participants must only be identified by number not by initials or name.

Storage of records
The signed copy of the consent form should be retained, along with the other forms relevant to the project, in a secure location at QMUL, accessible for inspection if required for at least seven years after the work is completed.
Researchers should note that in the event of a claim for an adverse reaction the signed consent form would need to be produced. In some instances, for example if required by the research funder or health and safety regulations, records should be kept for longer. Also, records of some research projects may have enduring significance beyond the life of the specific
project and should be kept for longer than the stipulated seven years, although researchers could not use the data for any other purpose.

At the end of the research the following records should be collated into one file and stored securely for the period specified on the application form, at the end of which

time the records may be destroyed:
• A copy of the research protocol
• A copy of the application to QMERC and its approval
• Copy of the data/results
• A copy of any publications arising from the research.

Please note that at least one Research Council (ESRC) now requires data to be transferred to its central data bank.

15 Information for participants

An adequate information sheet for participants is vital. It must be completed carefully following the guidelines given below and using the pro forma Information Sheet as a guide. This pro forma is attached to the application form.

The Information Sheet and consent form must be expressed in clear everyday language and any essential technical or academic terms must be explained.

A copy of the Information Sheet must be given to the participant to keep.

The Information Sheet must include the following:

1. The fact that participation is voluntary and refusal to participate will not give rise to any disadvantage or discrimination (*wording in the pro forma*);
2. Description of the nature and aims of the research project and the expected benefits;
3. A clear explanation of what will be required of, or happen to, the participant if he/she volunteers to take part and how long that involvement is likely to take;
4. A detailed description of any risks, inconvenience or discomfort that could arise, and any potential benefits to the volunteer as a result of their participation;
5. A precise and clear statement about the level of confidentiality or anonymity of the information to be gathered; if it is to be used anonymously the method of anonymisation should be indicated in non-technical terms;
6. If data is to be gathered about volunteers' physical or mental condition, there should be an appropriate undertaking about whether this will be reported to them, and in what way;
7. Whether and how the data will or might be published;
8. The name of the researcher(s) and contact details.
9. Insurance?

N.B You might like to ask someone outside the College to help, or put yourself in the position of a potential participant, when drafting your information and recruitment materials. It is likely that they will know nothing of research techniques nor of your subject so think about basic questions and explain what you mean in layman's terms.

16 Consent

This is fundamental to the ethics of a research project. Written consent from participants is normally required for all studies except those that are exclusively based on questionnaires and/or are not collecting sensitive data, in which case submitting a completed questionnaire implies consent (this should be stated on the

Information Sheet). If studies are to be published using data from an anonymous source e.g. student performance statistics, it may nevertheless be advisable, or at least courteous, to inform those concerned that the material is to be published.

In some cases e.g. where the study requires one-to-one interviews with senior professional people, agreement to be interviewed can be taken to imply consent provided this is made clear in the information sheet or letter of invitation. The information sheet must specify how the material will be used, whether it will anonymous or confidential or neither, and how it will be published.

You should refer to and amend the QMUL consent form attached to the application form to meet the needs of your study.

17 Signature of applicant and authorising signatories

The Principal Investigator should sign the application and submit it for approval to his/her Head of Department who should then also sign it. When the Principal Investigator is the Head of Department, the Head of School or other appropriate individual should give approval.

QMERC response

Once the Committee has reviewed your application, you will receive a written response within a few days which will advise you that your application is:

Approved
Approved with advisory points for you to incorporate
Approved conditionally: the conditions will be stated;
Referred to Full Committee: this is when members of a sub-board decide that the application is of a sort (higher risk etc.) that would be better viewed by all members.
Deferred: this is likely to be because the Committee requires further work or information;
Rejected

The Committee usually meets on Wednesdays with responses being sent to researchers early the following week. From 2013 2012/13, review panels will meet every three weeks and deadline for receipt of applications will be three weeks in advance.

NB Conditional approval or deferment is current for three months. If you have not responded to the Committee's requests within three months from the date of its response (even if you have not been able to meet the requests within that time), your application is automatically rejected, and, if you wanted to pursue the study, you would have to apply again.